



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

JUL 2 2004

Jean-François Boudier  
Scientific Director  
Ingredia  
51-53 Avenue F. Lobbedez, B.P 946  
62003 ARRAS Cedex  
France

Dear Mr. Boudier:

This is to inform you that the notification, dated April 13, 2004, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on April 29, 2004. Your notification concerns the substance "lactium™," a milk protein hydrolysate in powder, that you intend to market as a new dietary ingredient.

According to the notification, "lactium™" will be sold and incorporated in the form of oral serving (e.g., pills, tablets, gums) containing approximately 150 to 400 mg per capsule. Consumption of 1 oral serving per day will be suggested or recommended. Based on consumption of 1 oral serving per day, the maximum amount of "lactium™" that a consumer will receive is 400mg/day, which is the highest indicated quantity of "lactium™" that will be used in the dietary supplement, or approximately 6.67 mg/kg body weight/day for a 60 kg person.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.


In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your client must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification.

Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated, or misbranded.

Your notification will be kept confidential for 90 days after the filing date of April 29, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any further questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

  
*for* Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition